

**UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA**

TRAVANTI PHARMA, INC.,
f/k/a Birch Point Medical, Inc.,

Civil No. 04-2667 (JRT/FLN)

Plaintiff/Counterclaim Defendant,

**MEMORANDUM OPINION
AND ORDER**

v.

IOMED, INC.,

Defendant/Counterclaim Plaintiff.

Peter M. Lancaster and Kenneth E. Levitt, **DORSEY & WHITNEY, LLP**,
50 South Sixth Street, Suite 1500, Minneapolis, MN 55402, for plaintiff.

Christopher K. Larus and Christopher A. Young, **FULBRIGHT &
JAWORSKI, LLP**, 2100 IDS Center, 80 South Eighth Street,
Minneapolis, MN 55401; and David G. Magnum and David M. Bennion,
PARSONS, BEHLE & LATIMER, One Utah Center, 201 South Main
Street, Suite 1800, Post Office Box 45898, Salt Lake City, UT 84145, for
defendant.

Plaintiff Travanti Pharma, Inc. seeks summary judgment against defendant Iomed, Inc. on its patent infringement claims. Specifically, plaintiff asserts that defendant's product infringes claims 30, 46, 51 and 54 of plaintiff's U.S. Patent No. 6,653,014 ("the '014 patent"). Defendant seeks summary judgment on its claim for a declaratory judgment of non-infringement.

BACKGROUND

The products at issue in this case are disposable patches that use small amounts of electric power to deliver drugs directly through a patient's skin, without needles or pills.

This process is called “iontophoresis.” Through iontophoresis, positively-charged ions flow across the skin from the positive electrode, while negatively-charged ions flow across the skin from the negative electrode. Because electricity is used to deliver the drug through the skin of the patient, drug delivery ceases when power is cut off.

Plaintiff’s device, the Iontopatch, is a flexible patch that adheres to the skin like a thick band-aid, and is roughly shaped like an hourglass. The Iontopatch is powered by a pair of electrodes. The pair of electrodes consists of an oxidizable species and a reducible species. An “oxidizable species” means a material that is oxidizable, such that ions build up, or “oxidize,” on the material. A “reducible species” is a material that is reducible, such that it loses its ions, and the material is “reduced.” For example, in the Iontopatch, the “oxidizable species” is zinc, and the “reducible species” is silver-chloride.¹ The zinc, which is in a very thin layer and has roughly the surface area of a small coin, sits on one end of the patch, while the silver-chloride sits on the other end. The zinc and the silver-chloride are connected to each other by a “conductor,” which runs through the middle part of the patch. The “conductor” allows the ions to flow from the silver-chloride to the zinc.

The pair of electrodes on the Iontopatch will continue to provide power, and deliver drugs through the skin, until the zinc and silver-chloride have been fully oxidized and reduced. Once the zinc and silver-chloride have been fully oxidized and reduced, the pair of electrodes stops producing power, and drug delivery ceases. As a result, the amount of drug dosage that the patient receives is related to the power of the patch.

¹ The reducible species is actually silver-silver chloride, but is referred to as “silver-chloride” in this opinion for ease of reference.

In the Iontopatch, plaintiff determines how much zinc and silver-chloride to use in the patch based on the desired drug dosage. The Iontopatch is manufactured in a two-step process. In the first step, the zinc and silver-chloride electrodes are applied to the patch. The patch is then tested to confirm that the patch actually contains the correct amount of each electrode. If the patch does not contain the correct amount, then the second step is to adjust the patch so that it does contain the correct amount.

Defendant's patch, the Companion 80, is similar to plaintiff's patch. It is a disposable patch, roughly the same size and shape, and it also uses iontophoresis to deliver drugs to the patient. However, defendant's patch contains a watch battery that provides power to the patch. Defendant's patch also contains a pair of electrodes, although instead of using zinc and silver-chloride, it uses silver and silver-chloride.

The parties dispute the function of the electrodes in defendant's patch. It is undisputed that the majority of the power to the patch is supplied by the watch battery, and that the electrodes primarily regulate the flow of power from the battery. The parties dispute whether the electrodes provide power to the patch in addition to the battery.

The electrodes in defendant's patch are also connected to each other, but instead of using a single conductor as in the Iontopatch, the defendant's patch uses a number of conducting media.

Finally, there are differences in the manufacturing process between the two patches. In defendant's patch, the electrodes are applied in approximate amounts to the patch. Next, two different kinds of ink are applied over the electrodes. These two inks, "resistive carbon ink" and "dielectric ink," limit the flow of ions between the electrodes.

After the electrodes and the additional inks have been applied, the patch is tested. If the patch does not conform to the desired amounts of electrodes, the patch is discarded.

ANALYSIS

I. SUMMARY JUDGMENT STANDARD

Federal Rule of Civil Procedure 56(c) provides that summary judgment shall issue “if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(c); *see Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 252 (1986); *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). On a motion for summary judgment, the Court views the evidence in the light most favorable to the nonmoving party. *Ludwig v. Anderson*, 54 F.3d 465, 470 (8th Cir. 1995). The nonmoving party may not “rest on mere allegations or denials, but must demonstrate on the record the existence of specific facts which create a genuine issue for trial.” *Krenik v. County of Le Sueur*, 47 F.3d 953, 957 (8th Cir. 1995). Summary judgment on a patent infringement case is proper under the same circumstances as in any other case. *Goldenberg v. Cytogen, Inc.*, 373 F.3d 1158, 1163 (Fed. Cir. 2004).

II. PATENT INFRINGEMENT

Patent infringement is the unauthorized making, using, selling, offering to sell, or importing into the United States of any patented invention during the term of the patent. 35 U.S.C. § 271(a). A determination of infringement requires a two-step analysis.

Markman v. Westview Instruments, Inc., 52 F.3d 967, 981 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996). First, the court must construe the claims as a matter of law. *Id.* Second, the court compares the allegedly infringing device to the construed claims. *C. R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 861 (Fed. Cir. 2004). This step is a question of fact. *Bai v. L & L Wings, Inc.*, 160 F.3d 1350, 1353 (Fed. Cir. 1998). A trial court may not resolve infringement on summary judgment unless no genuine factual issue remains. *Bell Atl. Network Servs., Inc. v. Covad Commc'ns Group, Inc.*, 262 F.3d 1258, 1267 (Fed. Cir. 2001).

A. Claim Construction of the Disputed Terms

Claim construction is a question of law for the Court. *Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1344 (Fed. Cir. 2002). The words of the claim are generally given the ordinary and customary meaning they would have to a person of ordinary skill in the art in question at the time of invention. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005). To ascertain this meaning, courts look to the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning the meaning of technical terms and the state of the art. *Id.* at 1314.

The specification is the single best guide to the meaning of a disputed term. *Id.* at 1315. Courts must be cautious, however, not to read a limitation from the specification into the claims. *Id.* at 1320. The court should consider the prosecution history, if it is in evidence, but should be mindful that such history often lacks the clarity of the specification and is thus less useful for claim construction purposes. *Id.* at 1317. While

the court can use extrinsic evidence, it is less significant than the intrinsic record in determining the meaning of claim language. *Id.* at 1317. Such evidence must be considered in light of the intrinsic evidence, and it cannot be permitted to establish a meaning that is clearly at odds with the claim construction mandated by the intrinsic evidence. *Id.* at 1318.

The parties have raised three disputed terms for construction: “power source,” “altering,” and “conductor.”² For purposes of discussion, the Court will set forth each party’s proposed construction after each disputed term or phrase.

1. Power Source (claims 30, 46, 51, 54)³

Plaintiff a combination of galvanic and electrolytic power sources

Defendant generates, rather than consumes, power

The parties agree that the term “power source” means, at a minimum, something that generates, or contributes power to the patch. Plaintiff argues that the term “power source” also includes parts of the patch, which, although they may not individually generate power, are used to regulate the provision of power to the patch. Defendant responds that the term “power source” cannot include portions of the patch that do not directly generate power to the patch.

² Although plaintiff in its motion for summary judgment included the claim term “charge capacity” as a disputed term, at oral argument the parties confirmed that there was no dispute regarding “charge capacity.” Accordingly, the Court will not address this claim term.

³ Although the disputed terms often occur in claims other than those identified by the parties, the Court will limit itself to identifying those claims in which the parties indicate the disputed terms occur. In so doing, the Court notes that it has nevertheless considered each term in the context of the entire patent, including the specification and the unasserted claims.

The Court finds that defendant's proposed definition is the most appropriate construction of the term "power source." The ordinary and customary meaning of the term "power source," means something that is a source of, or generates, power. Further, this construction of the term "power source" is supported by the claim specification. In particular, the description of Figure 10 in the '014 specification refers to a patch that contains both a battery as well as electrodes, but makes clear that the pair of electrodes would provide power to the patch in addition to the battery:

Figure 10 represents a schematic diagram of another multiple-cell . . . embodiment of the power source . . . [with] an electrolytic battery or cell that produces **one volt**. To this is **added** . . . a galvanic cell [pair of electrodes] that also produces **one volt** . . . resulting in an overall total system that will theoretically produce a **two-volt** source

'014 Patent, col. 7, lines 24-59 (emphasis added). Expanding the meaning of "power source" to include portions of the patch that do not generate power, as plaintiff asserts, would be contrary to the ordinary and customary meaning, as understood by a person of ordinary skill in the art. Therefore, the Court construes the claim term "power source" to mean only parts of the patch that generate power, and parts of the patch that merely regulate the provision of power to the patch, but do not individually generate power, are not part of the "power source."

2. **Altering (claims 1, 30, 46, 50)**⁴

Plaintiff one or more techniques selected from the group consisting of adding, removing, isolating and shielding a known fraction of said initial amount

Defendant a two-phase manufacturing process in which a lot or test characterization is performed, and the initial amount of an oxidizable or reducible species is altered or adjusted to bring it within a desired or target.

For its proposed construction, defendant relies on the language in claims 30 and 46, which include the terms “initial amount” as the thing to be altered. (Def.’s Mem. in Opp’n, 20.) Based on the claim language, defendant argues that “the plain meaning of claim terms ‘initial amount’ or ‘original amount’ is the first or beginning amount of oxidizable and reducible species on each iontophoretic device . . . the plain meaning of the terms “altering” and ‘altered’ requires a change or variation from that beginning amount.” (*Id.* at 20.) Defendant also argues that the specification shows that the two-step process was necessary to avoid encompassing prior art. (Def.’s Mem. in Support Summ. J., 19.)

Plaintiff’s construction simply quotes the language of the claim itself. (’014 Patent, col. 8, lines 44-48.) Under plaintiff’s proposed construction, a two-phase process is not required. In addition, plaintiff notes that the prosecution history does not suggest that specifically a two-phase manufacturing process, rather than a one-step “altering” process, was necessary to avoid encompassing prior art.

The Court adopts plaintiff’s proposed construction of the term “altering.” First, plaintiff’s proposed construction relies on the claim language itself. *Phillips*, 415 F.3d at

⁴ For purposes of claim construction, the parties appear to use the words “altered,” “altering,” and “adjusting” interchangeably. The Court will also use them interchangeably.

1312-13. Second, defendant's construction of "altering" would impermissibly import the two-phase manufacturing process limitation from a dependent claim – claim 32 – into an independent claim – claim 30. *See Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 910 (Fed. Cir. 2004) ("the presence of a dependent claim that adds a particular limitation raises a presumption that the limitation in question is not found in the independent claim"). Therefore, the Court construes the claim term "altering" to mean: one or more techniques selected from the group consisting of adding, removing, isolating and shielding a known fraction of said initial amount.

3. Conductor

Plaintiff one or more conducting media connecting said amounts

Defendant a single conductor (rather than two or more conductors) that connects the oxidizable and reducible species and upon which the entire amounts of the oxidizable and reducible specie in each device rest, have access to, or are carried

The parties agree that the claim term "conductor" refers to a conducting medium. The parties dispute whether "conductor" means a single, common conductor, as defendant contends, or whether "conductor" means one or more conducting media, as plaintiff asserts.

The Court agrees with plaintiff's proposed construction. Contrary to defendant's proposed construction, there is nothing in the claim language that specifically states that only one conductor may be used. For example, claim 46(c) states:

one or more conducting media connecting said amounts of said oxidizable species and said reducible species, all of said amounts of said oxidizable species and said reducible species having access to a conducting medium

This claim refers to “**one or more conducting** media” and “a conducting medium” – not “**the** conducting medium,” as one would expect under defendant’s proposed construction. (’014 Patent, col. 11, lines 45-58 (emphasis added).)

Therefore, the Court construes the claim term “conductor” in the ’014 patent to mean “one or more conducting media.”

B. Infringement

Once the disputed claims are construed, the court compares the allegedly infringing device or process to the construed claims to determine if infringement has occurred. *C. R. Bard*, 388 F.3d at 861; *Corning Glass Works v. Sumitomo Elec. U.S.A. Inc.*, 868 F.2d 1251, 1258 (Fed. Cir. 1989). This is a question of fact that requires the patent holder to establish that the accused device includes every claim limitation or its equivalent. *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 29 (1997). Summary judgment is appropriate where the record shows “that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law.” Fed. R. Civ. P. 56(c); *Anderson*, 477 U.S. at 247. Accordingly, summary judgment of infringement is inappropriate if genuine factual issues remain. *Bell*, 262 F.3d at 1267.

Plaintiff asserts that defendant’s patch literally infringes product claims 46, 51, 54, and 30. Defendant denies that its patch infringes plaintiff’s patch.

1. Claim 46

Plaintiff asserts that defendant's patch literally infringes claim 46 of the '014 patent. Claim 46 states as follows:

46. An electrochemical power source comprising
- (a) one or more amount of oxidizable species;
 - (b) one or more amounts of reducible species;
 - (c) one or more conducting media connecting said amounts of said oxidizable species and said reducible species, all of said amounts of said oxidizable species and said reducible species having access to a conducting medium; and
 - (d) wherein at least one original amount of said one or more oxidizable species and said one or more reducible species has been altered to adjust the charge capacity of said power source.

('014 Patent, col. 11, lines 45-57.) Here, it is undisputed that defendant's patch contains both a battery and a pair of electrodes (the oxidizable species and the reducible species). The Court previously construed "power source" to mean something that generates power. Therefore, whether defendant's patch infringes claim 46 depends, in part, on whether the pair of electrodes in defendant's patch generates power and is a "power source."

The parties have offered conflicting evidence regarding whether the pair of electrodes in defendant's patch generates power. This is a genuine issue of material fact, rendering summary judgment inappropriate.

2. Claims 51 and 54

Plaintiff asserts that defendant's patch literally infringes claim 51 and 54 of the '014 patent.⁵ Both claims contain the term "power source" and are dependent on claim 46. As set forth above, the Court holds that there are genuine issues of material fact regarding Claim 46, including whether the electrodes in defendant's patch generate power and are therefore a "power source" as required by Claim 46. Because genuine issues of material fact precluded summary judgment on claim 46, summary judgment is also inappropriate on claims 51 and 54.

3. Claim 30

Plaintiff asserts that defendant's patch literally infringes claim 30 of the '014 patent. Claim 30 states as follows:

30. A method for adjusting the capacity of an electrochemical power source having an initial amount of an oxidizable material and an initial amount of a reducible material, wherein said initial amount of at least one of said oxidizable and said reducible materials has a target charge capacity range, comprising the step of altering the initial amount of at least one of said oxidizable material and said reducible material available to participate in said power source when necessary to conform the charge capacity to said target range by one or more techniques selected from the group consisting of adding,

⁵ Claim 51 states as follows: "A wearable, disposable iontophoretic delivery device including a power source as in claim 46." ('014 Patent, col. 12, lines 17-18.)

Claim 54 states as follows:

A device as in claim 51 wherein the original amount of one or more of said oxidizable species and said reducible species has been adjusted by a technique selected from the group consisting of addition, removal, isolation or shielding of a known amount of material to adjust the charge capacity of said electrochemical power sources.

('014 Patent, col. 12, lines 27-32.)

removing, isolating and shielding a known fraction of said initial amount.

(’014 Patent, col. 10, lines 28-39.)

The Federal Circuit has held that language appearing in the preamble also operates as a claim limitation when necessary to give meaning to the claim and properly define the invention. *Gerber Garment Tech., Inc. v. Lectra Systems, Inc.*, 916 F.2d 683, 688-89 (Fed. Cir. 1990) (“Where words in the preamble are necessary to give meaning to the claim and properly define the invention, they are deemed limitations of the claim”) (internal quotations omitted).

Here, the term “power source” is in the preamble to method claim 30, which sets forth the step of “altering” or “adjusting.” However, as made clear by the language of the claim itself, the step of “altering” or “adjusting” requires a “power source.” Indeed, the “power source” is the very thing that undergoes the step of “altering” or “adjusting.” It follows that if there is no “power source,” then there is nothing to “adjust” or “alter” within the scope of claim 30. Thus, although the term “power source” is in the preamble of claim 30, it is necessary to give meaning to the claim. *See Gerber Garment*, 916 F.2d at 688-89. Because there are genuine issues of material fact as to whether the electrodes in defendant’s patch generate power and therefore constitute a “power source,” summary judgment is inappropriate on claim 30.

This case will be placed on the Court’s next available trial calendar.

ORDER

Based on the foregoing, all the records, files, and proceedings herein, **IT IS HEREBY ORDERED** that:

1. The Court hereby **ADOPTS** the construction of the claim terms as set forth in the Memorandum accompanying this Order.

2. Plaintiff's Motion for Summary Judgment of Infringement [Docket No. 27] is **DENIED**.

3. Defendant's Motion for Summary Judgment of Noninfringement [Docket No. 17] is **DENIED**.

DATED: January 11, 2006
at Minneapolis, Minnesota.

s/ John R. Tunheim
JOHN R. TUNHEIM
United States District Judge